Docket No.: 12961/46501

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Breitenbach et al.
SERIAL NO.	:	10/533,683
FILED	:	April 26, 2005
FOR	:	TRANSDERMAL ADMINISTRATION OF (R)-3,3-DIPHENYLPROPYLAMIN-MONOESTERS
EXAMINER	:	Chukwuma O. Nwaonicha
GROUP ART UNIT	:	1621

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Alexandria, VA 22313-1450

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Signature: /Daniel G. Harris/
Daniel G. Harris

DECLARATION UNDER 37 C.F.R. §1.131

We, Armin Breitenbach, Claus Meese, Hans-Michael Wolff, and Roland Drews, declare the following:

1. We are the named co-inventors of the subject matter of claims 31-45 and 68 of United States Patent Application Serial No. 10/533,683 (the "present application").

2. Armin Breitenbach is a citizen of Germany. At the time of the invention of the subject matter of claims 31-45 and 68 of the present application, Armin Breitenbach was employed by Schwarz Pharma AG, the assignee of the present application.

3. Claus Meese is a citizen of Germany. At the time of the invention of the subject matter of claims 31-45 and 68 of the present application, Claus Meese was employed by Schwarz Pharma AG, the assignee of the present application. At the present time, Claus Meese is no longer employed by Schwarz Pharma AG but still receives certain payments from Schwarz Pharma AG.

4. Hans-Michael Wolff is a citizen of Germany. At the time of the invention of the subject matter of claims 31-45 and 68 of the present application, Hans-Michael Wolff was employed by Schwarz Pharma AG, the assignee of the present application. At the present time, Hans-Michael Wolff is employed by Schwarz Pharma AG.

5. Roland Drews is a citizen of Germany. At the time of the invention of the subject matter of claims 31-45 and 68 of the present application, Roland Drews was employed by Schwarz Pharma AG, the assignee of the present application. At the present time, Roland Drews is employed by Schwarz Pharma AG.

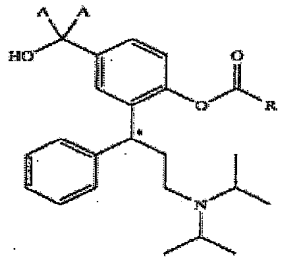
6. The acts described herein took place in Germany, a World Trade Organization member country, after January 1, 1996 and before February 27, 2003.

7. After January 1, 1996 and before February 27, 2003, we had completed the invention of claims 31-45 and 68 in Germany, as evidenced by the following.

8. Exhibit A is a copy of a research report prepared by Armin Breitenbach which summarizes our work in reducing to practice the invention of claims 31-45 and 68 of the present application.

9. The dates appearing in Exhibit A have been redacted but they are all after January 1, 1996 and before February 27, 2003.

10. Exhibit A describes the results of work in which we investigated the skin permeation characteristics of devices for transdermal delivery comprising the compound having the structure



where A is hydrogen, R is isopropyl, and the C-atom marked with a star "*" is present in the (R)-configuration. This compound is referred to in Exhibit A as "the free base of Fesoterodine" or as "SPM8224."

11. The devices described in Exhibit A were tested for the ability to deliver the free base of Fesoterodine across mouse and human skin. See, e.g., Exhibit A, page 1: "The report describes in vitro skin permeation characteristics of transdermal delivery systems (TDS) containing SPM8224, the free base of Fesoterodine." See also Exhibit A, page 1: "Patches were tested by means of flux rates across hairless mouse skin, selected sample were also investigated in the LACDR human skin model."

12. The delivery of the free base of Fesoterodine was measured in terms of the permeation across skin of the active metabolite of Fesoterodine, SPM7605.

13. The device described in Exhibit A also comprised a polymer matrix, in which the free base of Fesoterodine was present.

14. Several polymer matrices were tested. See, e.g., Exhibit A, page 5, Table 1 (reproduced below), which shows that the polymer matrices tested included: an acrylic adhesive (Duro Tak 387-2287), an ethyl vinyl acetate co-polymer adhesive (Dispofix 213), a silicon based adhesive (BioPSA), and a styrene block co-polymer.

Table 1: Properties of the patch batches

No	Lot No. (Ch.B.)	PSA	Theo. drug loading [% (w/w)]	Patch weight (n=10) [g/m²]
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SC Acrylic = solvent coating , acrylic type adhesive, Duro Tak 387-2287, National Starch & Chemical (NSC)
HM EVA = hot melt, ethylene vinyl acetate co-polymer adhesive, Dispofix 213, NSC
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HM SxS = hot melt, styrene block co-polymer, in house formulation
HM Acrylic 0x = hot melt acrylic type adhesives, experimental formulations from NSC, refer to Annex

15. The four types of polymer matrices mentioned in the preceding paragraph are the types of polymers recited in claim 34 of the present application ("acrylates, ethylene vinyl acetates (EVA), silicones or styrene block copolymers (SXS)").

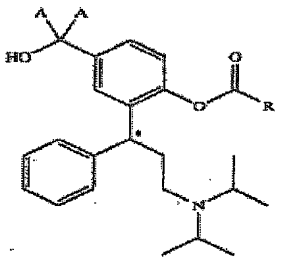
16. All four types of polymer matrices produced high flux rates through mouse skin. See Exhibit A, page 6, Figure 1 and the accompanying comment: "In all cases, high flux rates were observed ..."

17. The two polymer matrices that were tested in human skin produced high flux rates through human skin. See Exhibit A, page 8, Figure 3 and the accompanying comment: "After short lag-times, ... both batches showed a

high steady state flux for at least 2.5 d. From these results, patches with a size of already 20 cm^2 could theoretically deliver therapeutic doses of the free base of Fesoterodine, compared to the oral formulation."

18. The evidence presented in Exhibit A indicated that the devices tested in Exhibit A were able to deliver the free base of Fesoterodine through human skin in a dose of 0.5-20 mg per day. See, e.g., Exhibit A, page 1: "Based on these in vitro data patches with sizes in the range of 15 to 30 cm^2 could theoretically delivery [sic] 4 to 8 mg/24 h which is the current range of the oral Fesoterodine formulation." See also Exhibit A, page 9: "Based on the results obtained, the flux rates were found to be sufficient for the treatment of overactive bladder with patch sizes in the range of 15 to 30 cm^2 (equal to ca. 4 to 8 mg/24 h)."

19. At least as early as the date Exhibit A was prepared, we believed that the results described in Exhibit A for the free base of Fesoterodine predicted that similar results would be expected for compounds having the following structure:



wherein A is hydrogen or deuterium, R is C_{1-6}-alkyl, C_{3-10}-cycloalkyl or phenyl, which may each be substituted with C_{1-3}-alkoxy, fluorine, chlorine,

bromine, iodine, nitro, amino, hydroxyl, oxo, mercapto or deuterium and where the C-atom marked with a star "*" is present in the (R)-configuration.

20. Our belief referred to in the preceding paragraph is based on the similarity in structure between the free base of Fesoterodine and the compounds having the structure depicted in the preceding paragraph.

21. It is our opinion that those skilled in the art of transdermal delivery of pharmaceutical compounds would share the belief mentioned in paragraph 19 above.

22. Statements herein based on our own knowledge are true; statements herein based on information and belief are believed to be true. We acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, as provided for by 18 U.S.C. § 1001 and may jeopardize the validity or enforceability of any patent that may mature from the present application.

Signed 13. Dec., 2008 _____
Armin Breitenbach

Signed _____, 2008 _____
Claus Meese

Signed _____, 2008 _____
Hans-Michael Wolff

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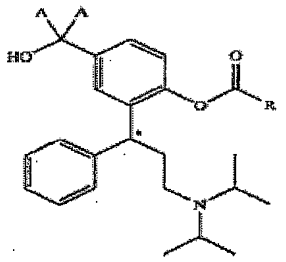
8. Exhibit A is a copy of a research report prepared by Armin Breitenbach which summarizes our work in reducing to practice the invention of claims 31-45 and 68 of the present application.

9. The dates appearing in Exhibit A have been redacted but they are all after January 1, 1996 and before February 27, 2003.

10. Exhibit A describes the results of work in which we investigated the skin permeation characteristics of devices for transdermal delivery comprising the compound having the structure



where A is hydrogen, R is isopropyl, and the C-atom marked with a star "*" is present in the (R)-configuration. This compound is referred to in Exhibit A as "the free base of Fesoterodine" or as "SPM8224."

11. The devices described in Exhibit A were tested for the ability to deliver the free base of Fesoterodine across mouse and human skin. See, e.g., Exhibit A, page 1: "The report describes in vitro skin permeation characteristics of transdermal delivery systems (TDS) containing SPM8224, the free base of Fesoterodine." See also Exhibit A, page 1: "Patches were tested by means of flux rates across hairless mouse skin, selected sample were also investigated in the LACDR human skin model."

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13. The device described in Exhibit A also comprised a polymer matrix, in which the free base of Fesoterodine was present.

14. Several polymer matrices were tested. See, e.g., Exhibit A, page 5, Table 1 (reproduced below), which shows that the polymer matrices tested included: an acrylic adhesive (Duro Tak 387-2287), an ethyl vinyl acetate co-polymer adhesive (Dispofix 213), a silicon based adhesive (BioPSA), and a styrene block co-polymer.

Table 1: Properties of the patch batches

No	Lot No. (Ch.B.)	PSA	Theo. drug loading [% (w/w)]	Patch weight (n=10) [g/m²]
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15. The four types of polymer matrices mentioned in the preceding paragraph are the types of polymers recited in claim 34 of the present application ("acrylates, ethylene vinyl acetates (EVA), silicones or styrene block copolymers (SXS)").

16. All four types of polymer matrices produced high flux rates through mouse skin. See Exhibit A, page 6, Figure 1 and the accompanying comment: "In all cases, high flux rates were observed ..."

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high steady state flux for at least 2.5 d. From these results, patches with a size of already 20 cm^2 could theoretically deliver therapeutic doses of the free base of Fesoterodine, compared to the oral formulation."

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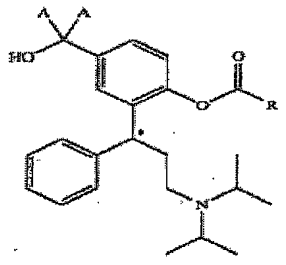
19. At least as early as the date Exhibit A was prepared, we believed that the results described in Exhibit A for the free base of Fesoterodine predicted that similar results would be expected for compounds having the following structure:



wherein A is hydrogen or deuterium, R is C_{1-6}-alkyl, C_{3-10}-cycloalkyl or phenyl, which may each be substituted with C_{1-3}-alkoxy, fluorine, chlorine,

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Signed _____, 2008 _____

Armin Breitenbach

Signed January 14, 2008 Dr. Claus D. Meese

Claus Meese

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Roland Drews

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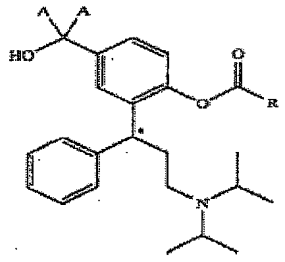

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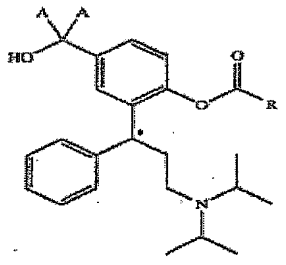

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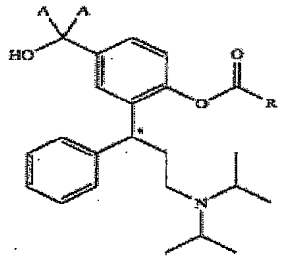


where A is hydrogen, R is isopropyl, and the C-atom marked with a star "*" is present in the (R)-configuration. This compound is referred to in Exhibit A as "the free base of Fesoterodine" or as "SPM8224."

11. The devices described in Exhibit A were tested for the ability to deliver the free base of Fesoterodine across mouse and human skin. See, e.g., Exhibit A, page 1: "The report describes in vitro skin permeation characteristics of transdermal delivery systems (TDS) containing SPM8224, the free base of Fesoterodine." See also Exhibit A, page 1: "Patches were tested by means of flux rates across hairless mouse skin, selected sample were also investigated in the LACDR human skin model."

12. The delivery of the free base of Fesoterodine was measured in terms of the permeation across skin of the active metabolite of Fesoterodine, SPM7605.

13. The device described in Exhibit A also comprised a polymer matrix, in which the free base of Fesoterodine was present.

14. Several polymer matrices were tested. See, e.g., Exhibit A, page 5, Table 1 (reproduced below), which shows that the polymer matrices tested included: an acrylic adhesive (Duro Tak 387-2287), an ethyl vinyl acetate co-polymer adhesive (Dispofix 213), a silicon based adhesive (BioPSA), and a styrene block co-polymer.

Table 1: Properties of the patch batches

No	Lot No. (Ch.B.)	PSA	Theo. drug loading [% (w/w)]	Patch weight (n=10) [g/m²]
1	20111080	SC acrylic	15	100
2	20111085	HM EVA	15	84
3	20111086	HM silicone	15	63
4	20111087	HM SxS	15	89
5	20111095	HM acrylic 01	15	73
6	20201027	HM acrylic 02	15	121
7	20201028	HM acrylic 03	15	115

SC Acrylic = solvent coating , acrylic type adhesive, Duro Tak 387-2287, National Starch & Chemical (NSC)
HM EVA = hot melt, ethylene vinyl acetate co-polymer adhesive, Dispofix 213, NSC
HM Silicone = hot melt silicone based adhesive, BioPSA + 5% (w/w) Ozokerite wax, DowCorning
HM SxS = hot melt, styrene block co-polymer, in house formulation
HM Acrylic 0x = hot melt acrylic type adhesives, experimental formulations from NSC, refer to Annex

15. The four types of polymer matrices mentioned in the preceding paragraph are the types of polymers recited in claim 34 of the present application ("acrylates, ethylene vinyl acetates (EVA), silicones or styrene block copolymers (SXS)").

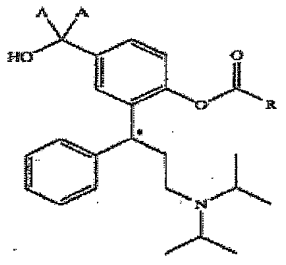
16. All four types of polymer matrices produced high flux rates through mouse skin. See Exhibit A, page 6, Figure 1 and the accompanying comment: "In all cases, high flux rates were observed ..."

17. The two polymer matrices that were tested in human skin produced high flux rates through human skin. See Exhibit A, page 8, Figure 3 and the accompanying comment: "After short lag-times, ... both batches showed a

high steady state flux for at least 2.5 d. From these results, patches with a size of already 20 cm^2 could theoretically deliver therapeutic doses of the free base of Fesoterodine, compared to the oral formulation."

18. The evidence presented in Exhibit A indicated that the devices tested in Exhibit A were able to deliver the free base of Fesoterodine through human skin in a dose of 0.5-20 mg per day. See, e.g., Exhibit A, page 1: "Based on these in vitro data patches with sizes in the range of 15 to 30 cm^2 could theoretically delivery [sic] 4 to 8 mg/24 h which is the current range of the oral Fesoterodine formulation." See also Exhibit A, page 9: "Based on the results obtained, the flux rates were found to be sufficient for the treatment of overactive bladder with patch sizes in the range of 15 to 30 cm^2 (equal to ca. 4 to 8 mg/24 h)."

19. At least as early as the date Exhibit A was prepared, we believed that the results described in Exhibit A for the free base of Fesoterodine predicted that similar results would be expected for compounds having the following structure:



wherein A is hydrogen or deuterium, R is C_{1-6}-alkyl, C_{3-10}-cycloalkyl or phenyl, which may each be substituted with C_{1-3}-alkoxy, fluorine, chlorine,

bromine, iodine, nitro, amino, hydroxyl, oxo, mercapto or deuterium and where the C-atom marked with a star "*" is present in the (R)-configuration.

20. Our belief referred to in the preceding paragraph is based on the similarity in structure between the free base of Fesoterodine and the compounds having the structure depicted in the preceding paragraph.

21. It is our opinion that those skilled in the art of transdermal delivery of pharmaceutical compounds would share the belief mentioned in paragraph 19 above.

22. Statements herein based on our own knowledge are true; statements herein based on information and belief are believed to be true. We acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, as provided for by 18 U.S.C. § 1001 and may jeopardize the validity or enforceability of any patent that may mature from the present application.

Signed _____, 2008 _____

Armin Breitenbach

Signed _____, 2008 _____

Claus Meese

Signed _____, 2008 _____

Hans-Michael Wolff

Signed 10. Dez, 2008 Roland Drews

Roland Drews